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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,198	04/15/2004	Maria Alexandra Glucksmann	MPI00-064CP1CN1DV1M	7650

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,198	GLUCKSMANN ET AL.	
	Examiner	Art Unit	
	Yong D. Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 11-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of 10/314,881, now issued as US Patent No. 6,767,727, which is a continuation of 09/773,426, now issued as US Patent No. 6,534,302, which is a continuation in part of 09/495,823, now issued as US Patent No. 6,780,627.

Claims 1-26 are pending. Claims 1-7 and 11-25 are withdrawn. Claims 8-10 and 26 are under consideration.

Election/Restrictions

Applicant's election of Group I (claims 8-10 and 26, drawn in part to SEQ ID NO:3) in the reply filed on September 11, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-7 and 11-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 8, 2006.

Claims 8-9 are partially directed to non-elected inventions (polynucleotide of SEQ ID NO:2, 6, 7, 8, 11, 13 and 14, cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1846 and polypeptide of SEQ ID NO:1, 5, 7 or encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-

1846). For examination purposes, the Examiner will only examine the elected invention, polypeptide comprising SEQ ID NO:3, polypeptide encoded by SEQ ID NO:4, 12 or the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1639,. and said polypeptide further comprising heterologous amino acid sequences and a pharmaceutical composition comprising said polypeptide.

Notice of Possible Rejoinder: The Examiner notes that if claim 8 is found directed to an allowable product, then 20-23, which are directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would then be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also MPEP 821.04, *In re Ochiai,* and *In re Brouwer*). Since process claims 20-23 would be rejoined and fully examined for patentability under 37 CFR 1.104 upon allowance of claim 8, applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Priority

Applicants' claim to domestic priority under 35 USC 121 to US non-provisional application 10/314,881, filed December 9, 2002, is acknowledged. Applicants' claim to domestic priority under 35 USC 121 to US non-provisional application 09/773,426, filed January 31, 2001, is acknowledged. Applicants' claim to domestic priority under 35 USC 121 to US non-provisional application 09/495,823, filed January 31, 2000, is

acknowledged. The sequences of SEQ ID NOs: 3-4 and 12 of the instant application are disclosed in Figure 5 in the drawing of 09/495,823.

Drawings

When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. MPEP 2422.02. See particularly drawing figures 4, 8, 13 and 18.

Information Disclosure Statement

With the exception of the references that are crossed out, the initialed references cited in the information disclosure statement (IDS) submitted on September 19, 2006 are in compliance with the provisions of 37 CFR 1.97. Reference ""Blas Searches (7)", EMBL Database Report for Accession No. AB023218", "EMBL Database Report for Accession No. AI423178" and "GenBank Report" have not been considered because the citations do not comply with the provision of 37 CFR 1.97 by providing the correct author. For example, for the reference "GenBank Report", the correct author is KIKUNO et al. A copy of the initialed form PTO-1449 is attached. The references cited on the form PTO-1449 of the instant application were previously submitted in its parent application, 09/462,845, 09/773,426 and/or 10/314,881.

Specification

Examiner notes that applicants have not updated the relationship of the instant application to its parent applications (09/495,823, 09/773,426 and 10/314,881) that has matured into a US patent (U.S. Patent No. 6,780,627, 6,534,302 and 6,767,727, respectively). Examiner urges applicants to amend said information by providing the US patent number in response to this Office action.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: -- A Polypeptide Having Sulfatase Activity-- .

The disclosure is objected to because it contains many embedded hyperlink and/or other form of browser-executable code throughout the specification, page 26, line 10, page 27, line 2, page 37, line 4 and page 95, line 13, for example. Applicant is required to delete all the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Appropriate correction is required.

The use of the trademark "Microsoft Word" and "WordPerfect" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as

trademarks. Applicant's cooperation is requested in reviewing the specification for additional trademarks that may be present in the specification and making the appropriate

Claim Objections

Claim 8 is objected to because of the following informalities:

Claim 8 recites "biological active". It appears that applicants have meant to recite "biologically active". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 and claims 9-10 and 26 depending therefore are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the phrase "hybridizes... under stringent conditions". The metes and bounds of the phrase in the context of the above claim are not clear. While "stringent conditions" are disclosed in the specification (page 54, line 26 through page 55, line 17), it is unclear as to which of these conditions, if any, are meant as being a "stringent condition". Therefore, it is not clear to the Examiner as to what hybridization conditions are encompassed in the phrase. Examiner requests clarification of the

above phrase by amending the phrase to recite a specific stringent condition. For examination purposes, the above term has been interpreted as encompassing any hybridization condition.

Claim 8 and claims 9-10 and 26 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the terms "biological active polypeptide" and "polypeptide has biological activity". The metes and bounds of these terms in the context of the above claim are not clear to the Examiner. The terms encompass many different activities, such as enzymatic activity and ability to illicit antibodies, which can be considered as "biological activity", and therefore is outside the scope of the invention. A perusal of the specification did not provide the Examiner with a specific definition for the above terms. Therefore, it is not clear to the Examiner either from the specification or from the claim as to what specific activities of the polypeptide are encompassed in "biological active" and "biological activity". Examiner requests clarification of the above terms. For examination purposes, the above terms have been interpreted as "polypeptides having any activity".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to **(A)** a polypeptide having at least 60% sequence identity to SEQ ID NO:4 or 12 or the polypeptide encoded by the cDNA insert of the plasmid of PTA-1639, **(B)** a naturally allelic variant of SEQ ID NO:3 or the polypeptide encoded by the cDNA insert of the plasmid of PTA-1639, wherein the polypeptide is encoded by a polynucleotide that hybridizes to the complement of SEQ ID NO:4 or SEQ ID NO:12 and **(C)** a polypeptide comprising a fragment of at least 15 amino acids of SEQ ID NO:3 or the polypeptide encoded by the cDNA insert of the plasmid of PTA-1639, **(D)** polypeptide of **(A), (B)** or **(C)** further comprising heterologous amino acid sequences and wherein the function of the resulting fusion polypeptide is not recited and **(E)** a pharmaceutical composition comprising the polypeptide of **(A)**, **(B)** or **(C),** wherein function of the polypeptides **(A)-(C)** are not recited.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." The examiner has broadly interpreted "biological active polypeptide" and "polypeptide having biological activity" to encompass polypeptides having any activity. Therefore, the polypeptides of the claims encompass polypeptides having any function. Also, the examiner has broadly interpreted "stringent conditions" to encompass any hybridization conditions. (See the rejection of the terms "biological active polypeptide", "polypeptide having biological

activity" and "stringent condition" under 35 USC 112, 2nd paragraph, for Examiner's interpretation of the terms.) Further, the examiner has broadly interpreted "an amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1639" of claim 9 to encompass a fragment of as few as 2 contiguous amino acids of SEQ ID NO:3. Thus, claim 9 has been construed as meaning any polypeptides comprising as few as two contiguous amino acids of SEQ ID NO:12. Further, regarding claim 10, the specification describes that heterologous peptides can be "fused to the N-terminus or C-terminus of the sulfatase polypeptide or can be internally located" (page 32, lines 17-20), wherein the resulting fusion polypeptide does not affect sulfatase activity and fusion polypeptide that "directly affects sulfatase functions" (page 32, line 21 through 34, line 6). Therefore, claim 10 encompasses sulfatase comprising heterologous amino acid sequences fused at its N-terminus, C-terminus or interspersed within its structure, wherein the resulting fusion protein continues to have sulfatase activity, no activity or unknown activity.

Therefore, the claims are drawn to a genus comprising polypeptides having unknown function.

In *University of Calfornia v. Eli Lilly & Co.*, 43 USPQZd 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, (or) chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP 2163, the written description requirement for a claimed genus may be satisfied through sufficient

description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

In the instant case, the claims are drawn to many functionally unrelated polypeptides encompassed within the scope of these clams, including partial sequences, resulting in a substantial variation within the genus. The genus of these polypeptides comprise a large variable genus encompassing many different polypeptides having different activity or no activity. The specification only describes one species, polypeptide having the amino acid sequence of SEQ ID NO:3 and having glucosamine-6-sulfatase activity, a pharmaceutical composition comprising said polypeptide and said polypeptide fused to heterologous amino acids at its N-terminus or C-terminus, wherein the resulting polypeptide continues to have glucosamine-6-sulfatase activity. While MPEP 2163 acknowledges that in certain situations "one species adequately supports a genus," it also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely

variant species cannot be achieved by disclosing only one species within the genus." In view of the widely variant species encompassed by the genus, this one example is not enough and does not constitute a representative number of species to describe the whole genus of a fusion protein having unknown function. The specification fails to describe additional representative species of the polypeptides by any identifying characteristics or properties of the polypeptides, for which no predictability of function is apparent. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The claims also encompass naturally occurring allelic variants of SEQ ID NO:3. The specification defines "naturally occurring allelic sequence" as an alternative form of the gene which may result in at least one mutation in the nucleic acid sequence, which are found in nature (page 53, lines 25-28). Alleles may result in altered mRNAs or polypeptides whose structure or function may or may not be altered. Alleles may result in altered mRNAs or polypeptides whose structure or function may or may not be altered. This definition does not provide any specific information about the structure of the naturally occurring (alleles) variants of SEQ ID NO:3 (i.e. where in the regions within which mutations are likely to occur) nor discloses any function for the naturally occurring variants. There is no description of the mutational sites that exist in nature, and there is no description of how the structure of SEQ ID NO:3 relates to the structure of any naturally occurring alleles. The general knowledge in the art concerning alleles does not provide any indication of how one allele is representative of unknown alleles. The

nature of alleles is such that they are variant structures, and in the present state of the art, structure of one does not provide guidance to the structure others.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 8-10 and 26.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 8-10 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel plasmid. Since the plasmid is essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmid's sequence is not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plasmid. The specification does not disclose a repeatable process to obtain the plasmid and it is not apparent if the DNA

sequences are readily available to the public. Accordingly, it is deemed that a deposit of the plasmid should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that if applicants have deposited the plasmid, it must be public available. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that: 1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request; 2. upon granting of the patent the strain will be available to the public under the conditions specified in 37 CFR 1.808; 3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and 4. the deposit will be replaced if it should ever become inviable.

Claims 8-10 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) a polypeptide encoded by the polynucleotide of SEQ ID NO:4, 12 or the cDNA insert of the plasmid PTA-1639, (2) a

polypeptide comprising the amino acid sequence of SEQ ID NO:3, (3) polypeptide of (1) or (2) fused to heterologous amino acid sequences and the resulting fused polypeptide continues to have glucosamine-6-sulfatase activity and (4) a pharmaceutical composition comprising the polypeptide of (1) or (2), does not reasonably provide enablement for to **(A)** a polypeptide having at least 60% sequence identity to SEQ ID NO:4 or 12 or the polypeptide encoded by the cDNA insert of the plasmid of PTA-1639, **(B)** a naturally allelic variant of SEQ ID NO:3 or the polypeptide encoded by the cDNA insert of the plasmid of PTA-1639, wherein the polypeptide is encoded by a polynucleotide that hybridizes to the complement of SEQ ID NO:4 or SEQ ID NO:12, **(C)** a polypeptide comprising a fragment of at least 15 amino acids of SEQ ID NO:3 or the polypeptide encoded by the cDNA insert of the plasmid of PTA-1639, **(D)** polypeptide of **(A), (B)** or **(C)** further comprising heterologous amino acid sequences and wherein the function of the resulting fusion polypeptide is not recited and **(E)** a pharmaceutical composition comprising the polypeptide of **(A), (B)** or **(C),** wherein the polypeptides of **(A)-(D)** have unknown structure and/or have unknown function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4)

the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to **(A)** a polypeptide having at least 60% sequence identity to SEQ ID NO:4 or 12 or the polypeptide encoded by the cDNA insert of the plasmid of PTA-1639, **(B)** a naturally allelic variant of SEQ ID NO:3 or the polypeptide encoded by the cDNA insert of the plasmid of PTA-1639, wherein the polypeptide is encoded by a polynucleotide that hybridizes to the complement of SEQ ID NO:4 or SEQ ID NO:12 and **(C)** a polypeptide comprising a fragment of at least 15 nucleotides of SEQ ID NO:3 or the polypeptide encoded by the cDNA insert of the plasmid of PTA-1639, **(D)** polypeptide of **(A), (B)** or **(C)** further comprising heterologous amino acid sequences and wherein the function of the resulting fusion polypeptide is not recited and **(E)** a pharmaceutical composition comprising the polypeptide of **(A)**, **(B)** or **(C),** wherein function of the polypeptides **(A)-(C)** are not recited.

The breadth of the claims.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." The examiner has broadly interpreted "biological active polypeptide" and "polypeptide having biological activity" to encompass polypeptides having any activity. Therefore, the polypeptides of the claims encompass polypeptides having any function. Also, the examiner has broadly interpreted "stringent conditions" to encompass any hybridization conditions. (See the rejection of the terms "biological active polypeptide", "polypeptide having biological

activity" and "stringent condition" under 35 USC 112, 2nd paragraph, for Examiner's interpretation of the terms.) Further, the examiner has broadly interpreted "an amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1639" of claim 9 to encompass a fragment of as few as 2 contiguous amino acids of SEQ ID NO:12. Thus, claim 9 has been construed as meaning any polypeptides comprising as few as two contiguous amino acids of SEQ ID NO:3. Further, regarding claim 10, the specification describes that heterologous peptides can be "fused to the N-terminus or C-terminus of the sulfatase polypeptide or can be internally located" (page 32, lines 17-20), wherein the resulting fusion polypeptide does not affect sulfatase activity and fusion polypeptide that "directly affects sulfatase functions" (page 32, line 21 through 34, line 6). Therefore, claim 10 encompasses sulfatase comprising heterologous amino acid sequences fused at its N-terminus, C-terminus or interspersed within its structure, wherein the resulting fusion protein continues to have sulfatase activity, no activity or unknown activity. Therefore, the claims are drawn to a genus comprising fusion polypeptides having unknown function.

Therefore, claims 8-10and 26 are drawn to polypeptides having unknown structure and/or have unknown function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides of virtually any structure and/or function or polypeptides/fragments having virtually any structure and/or function. In the instant case, the specification enables a polypeptide having the amino acid sequence of SEQ

ID NO:3 and having glucosamine-6-sulfatase activity, a pharmaceutical composition comprising said polypeptide and said polypeptide fused to heterologous amino acids at its N-terminus or C-terminus, wherein the resulting polypeptide continues to have glucosamine-6-sulfatase activity.

The quantity of experimentation required to practice the claimed invention based on the teachings of the specification.

While enzyme isolation techniques, recombinant and mutagenesis techniques were known in the art at the time of the invention, e.g. hybridization or mutagenesis, and it is routine in the art to screen for variants comprising multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within the encoded protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. Furthermore, while the skilled artisan can produce variants of the polypeptide of SEQ ID NO:3 having the recited structural characteristics using well-known and widely used techniques in the art, the amount of experimentation required is not routine due to the fact that the number of species encompassed by the claims is extremely large. For example, Guo et al.(*Proc Natl Acad Sci USA*. 2004 Jun 22;101(25):9205-10 – form PTO-892) teaches that the percentage of random single substitution mutations which inactivate a protein for the protein 3-methyladenine DNA glycosylase is 34% (*x* factor)

and that this number appears to be consistent with other studies in other proteins as well (Abstract). Guo et al. further shows in Table 1 that the percentage of active mutants for multiple mutants appears to be exponentially related to this by the simple formula $(.66)^x$ x 100% where x is the number of mutations introduced and 0.66 is the probability of a protein to remain active after one amino acid change (0.66= 1-0.34). If one were to apply this estimate to the instant case, for polynucleotides encoding polypeptides having 60% sequence identity to SEQ ID NO: 3 (871 amino acids; 348 mismatches = 0.40x871), only $(.66)^{348}$ x 100% or 1.6 x 10^{-61}% of random mutants having 60% sequence identity to SEQ ID NO:3 would be active. As indicated above, 60% sequence identity to SEQ ID NO: 3 allows for 348 amino acid changes. Therefore, to find a single active mutant within random mutants having 60% sequence identity to SEQ ID NO:3, one of skill in the art would have to screen close to over a gargantuan number of mutants (100/6.9 x 10^{-61}%). For a polypeptide encoded by a fragment that comprises of at least **15** amino acids, or a polypeptide having less than 2% (15/871x100%) sequence identity to SEQ ID NO:3, to find a single active mutant, it would be an almost impossible undertaking to one having ordinary skill in the art and the above calculations would be superfluous.

In the absence of: (a) rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function and (b) a correlation between structure and glucosamine-6-sulfatase activity, the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. One of skill in the art would have to test these infinite possible

polypeptides to determine (1) which ones have glucosamine-6-sulfatase activity, (2) the specific substrates targeted by such proteins and (3) how to use those polypeptides encompasses by the claims which do not have glucosamine-6-sulfatase activity. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, as is the case herein, the specification must provide a reasonable amount of guidance which respect to the direction in which the experimentation should proceed so that a reasonable number of species can be selected for testing. In view of the fact that such guidance has not been provided in the instant specification, it would require undue experimentation to enable the full scope of the claims.

The state of prior art, the relative skill of those in the art, and predictability or unpredictability of the art.

Since the amino acid sequence of the protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. In the instant case, neither the specification or the art provide a correlation between structure and activity such that one of skill in the art can envision the structure of any polypeptides having the same biological function as that of the polypeptide of SEQ ID NO:3 or predict the function of a polypeptide from its primary structure. In addition, the art does not provide any teaching or guidance as to (1) which amino acids within the

polypeptides encoded by SEQ ID NO: 4 or 12 can be modified and which ones are conserved such that one of skill in the art can make the recited polynucleotides encoding polypeptides having the same enzymatic activity as that of the polypeptide of SEQ ID NO:3, (2) which segments of the polypeptide of SEQ ID NO:3 are essential for activity, and (3) the general tolerance of glucosamine-6-sulfatase proteins to structural modifications and the extent of such tolerance. The art clearly teaches that changes in a protein's amino acid sequence to obtain the desired activity without any guidance/knowledge as to which amino acids in a protein are required for that activity is highly unpredictable. At the time of the invention there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity. For example, Branden et al. (introduction to Protein Structure, Garland Publishing Inc., New York, page 247, 1991) teach that (1) protein engineers are frequently surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes, (2) the often surprising results obtained by experiments where single mutations are made reveal how little is known about the rules of protein stability, and (3) the difficulties in designing de novo stable proteins with specific functions.

Further, the function of a polypeptide cannot be predicted from its structure and the specification does not teach how to use polypeptides having any function or having no activity. The quantity of experimentation in this area is extremely large since there is significant variability in the activity of the polynucleotides in the claims. It would require significant study to identify the actual function of the encoded polypeptides and

identifying a use for the encoded polypeptide would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Further, the art is extremely unpredictable with regard to protein function in the absence of realizable information regarding its activity. Even very similar proteins may have every different functions. In the current case, where no specific information is known regarding the function, it is entirely unpredictable what function and activity will be found for the protein. The prior art does not resolve this ambiguity, since no prior art activity is identified for the encoded polypeptides.

The amount of direction or guidance presented and the existence of working examples.

The specification discloses only a polypeptide having the amino acid sequence of SEQ ID NO:3 and having glucosamine-6-sulfatase activity, a pharmaceutical composition comprising said polypeptide and said polypeptide fused to heterologous amino acids at its N-terminus or C-terminus, wherein the resulting polypeptide continues to have glucosamine-6-sulfatase activity. However, the speciation fails to provide any information as to (1) specific substrates associated with the glucosamine-6-sulfatase of SEQ ID NO:3, (2) structural elements required in a polypeptide having glucosamine-6-sulfatase activity, or (3) which are the structural elements in the polypeptide of SEQ ID NO:3 that are essential to display glucosamine-6-sulfatase activity. No correlation between structure and function of having glucosamine-6-sulfatase activity has been

presented. There is no information or guidance as to which amino acid residues in the polypeptides encoded by SEQ ID NO: 4 or 12 can be modified and which ones are to be conserved to create a polypeptide displaying the same activity as that of the polypeptides of SEQ ID NO:3.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability of the prior art in regard to structural changes and their effect on function and the lack of knowledge about a correlation between structure and function, an undue experimentation would be necessary one having ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides having the desired biological characteristics recited in the claim are unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 8 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Kikuno et al.

Claims 8-9 are drawn to a polypeptide having at least 60% sequence identity to SEQ ID NO:3 of the instant invention.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." The examiner has broadly interpreted "biological active polypeptide" and "polypeptide having biological activity" to encompass polypeptides having any activity. (See the rejection of the terms "biological active polypeptide" and "polypeptide having biological activity" under 35 USC 112, 2nd paragraph, for Examiner's interpretation of the term.) Therefore, the polypeptides of the

claims encompass polypeptides having any function or enzymatic activity, such as sulfatase activity.

Kikuno et al. (DNA Res. 1999 Jun 30;6(3):197-205 – form PTO-1449) discloses a polypeptide having 100% sequence identity to SEQ ID NO:3 of the instant invention and has sulfatase activity (see Table 2-2 "KIAA1077" and see attached sequence alignments "Kikuno et al."). Therefore, the reference of Kikuno et al. anticipates claims 8-9.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Robertson et al.

Claim 9 is drawn to a polypeptide comprising an amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1639.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." The examiner has broadly interpreted "an amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1639" of claim 9 to encompass a fragment of as few as 2 contiguous amino acids of SEQ ID NO:3. Thus, claim 9 has been construed as meaning any polypeptides comprising as few as two contiguous amino acids of SEQ ID NO:3. Further, the examiner has broadly interpreted "biological active polypeptide" and "polypeptide having biological activity" to encompass polypeptides having any activity. (See the rejection of the terms "biological active

polypeptide" and "polypeptide having biological activity" under 35 USC 112, 2nd paragraph, for Examiner's interpretation of the term.) Therefore, the polypeptides of the claims encompass polypeptides having any function or any enzymatic activity.

Robertson et al. (Biochem J. 1992 Dec 1;288 (Pt 2):539-44 – form PTO-892) discloses a polypeptide comprising at least two contiguous amino acids of SEQ ID NO:3 and having glucose-6-sulfatase activity (see Figure 2 on page 542, abstract and see attached sequence alignment "Robertson et al."). Therefore, the reference of Robertson et al. anticipates claim 9.

Claims 8-10 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Emmerson et al.

Claims 8-10 and 26 are drawn to a polypeptide having at least 60% sequence identity to SEQ ID NO:3 of the instant invention, said polypeptide further comprising heterologous sequences and a pharmaceutical composition comprising said polypeptide and a polypeptide comprising an amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1639.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." The examiner has broadly interpreted "biological active polypeptide" and "polypeptide having biological activity" to encompass polypeptides having any activity. (See the rejection of the terms "biological active polypeptide" and "polypeptide having biological activity under 35 USC 112, 2nd paragraph, for Examiner's interpretation of the term.) Therefore, the polypeptides of the

claims encompass polypeptides having any function or enzymatic activity, such as sulfatase activity. Further, the examiner has broadly interpreted "an amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1639" of claim 9 to encompass a fragment of as few as 2 contiguous amino acids of SEQ ID NO:3. Thus, claim 9 has been construed as meaning any polypeptides comprising as few as two contiguous amino acids of SEQ ID NO:3.

Emerson et al. (US Patent 6,562,956 B1– form PTO-892) discloses a polypeptide having sulfatase activity, wherein said polypeptide is 94.3% identical to the polypeptide of SEQ ID NO:3 of the instant invention and is 100% identical to amino acids 54-871 of SEQ ID NO:3 of the instant invention (Column 1, lines 19-65 and Column 39-52 and see attached sequence alignment "Emerson et al."). Therefore, the polypeptide of Emerson et al. (1) has at least 60% sequence identity to SEQ ID NO:3 of the instant invention and has biological activity and (2) comprises an amino acid sequence, as little as two amino acids of SEQ ID NO:3, and has biological activity. Emerson et al. also discloses said polypeptide further comprising heterologous sequences attached at its N-terminus (Column 8, lines 15-18) and a pharmaceutical composition comprising said polypeptide (Column 10, lines 49-53). Therefore, the reference of Emerson et al. anticipates claims 8-10 and 26.

Examiner notes that US Patent 6,797,816 is a continuation of US Patent 6,562,956 and does not claim a polypeptide anticipating the claimed invention. Examiner has made one rejection based on US Patent 6,562,956 instead of multiple rejections because all of these references have a common assignee, US Patent

6,797,816 is a continuation of US Patent 6,562,956, US Patent 6,797,816 does not claim the subject matter of the instant invention and since antedating the filing date of US Patent 6,562,956 or showing that disclosure relied on is applicant's own work will obviate rejections based on the above reference.

Claims 8-10 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashkenazi et al.

Claims 8-10 and 26 are drawn to a polypeptide having at least 60% sequence identity to SEQ ID NO:3 of the instant invention, said polypeptide further comprising heterologous sequences and a pharmaceutical composition comprising said polypeptide and a polypeptide comprising an amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1639.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." The examiner has broadly interpreted "biological active polypeptide" and "polypeptide having biological activity" to encompass polypeptides having any activity. (See the rejection of the terms "biological active polypeptide" and "polypeptide having biological activity" under 35 USC 112, 2nd paragraph, for Examiner's interpretation of the term.) Therefore, the polypeptides of the claims encompass polypeptides having any function or enzymatic activity, such as sulfatase activity. Further, the examiner has broadly interpreted "an amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1639" of claim 9 to encompass a fragment of as few as 2

contiguous amino acids of SEQ ID NO:3. Thus, claim 9 has been construed as meaning any polypeptides comprising as few as two contiguous amino acids of SEQ ID NO:3.

Ashkenazi et al. (US Patent Application No. 2003/0082546 A1 – form PTO-892) discloses polypeptide having sulfatase activity, wherein said polypeptide is 66.8% identical to the polypeptide of SEQ ID NO:3 of the instant invention ([563]-[565] and see attached sequence alignment "Ashkenazi et al."). Therefore, the polypeptide of Ashkenazi et al. (1) has at least 60% sequence identity to SEQ ID NO:3 of the instant invention and has biological activity and (2) comprises an amino acid sequence, as little as two amino acids of SEQ ID NO:3, and has biological activity. Ashkenazi et al. also discloses said polypeptide further comprising heterologous sequences attached at its N-terminus (abstract and claims 12 and 14-16) and a pharmaceutical composition comprising said polypeptide ([581]). Therefore, the reference of Ashkenazi et al. anticipates claims 8-10 and 26.

Examiner notes that Goddard et al. (US Patent No. 7,034,136 B2- form PTO-892), Desnoyers et al. (US Patent No. 6,930,170 B2, US Patent No. 6,953,836, US Patent No. 6,956,108 B2, US Patent No. 6,972,185 B2, US Patent No.7,019,116 B2, US Patent No.7,029,873 B2, US Patent No. 7,034,122 B2, US Patent No. 7,034,106 B2 – form PTO-892) and Botsein et al. (US Patent No. 7,018,811 B2 and US Patent No. 6,913,919 B2- form PTO-892) are all continuations of Ashkenazi et al. - US Patent Application No. 2003/0082546 A1 (09/941,992). Examiner has made one rejection based on Askenazi et al. instead of multiple rejections because all of these references have a common assignee (Genetech, Inc), all are continuations of 09/941,992, none of

the references claim the subject matter of the instant invention and antedating the filing date of 09/941,992 or showing that disclosure relied on is applicant's own work will obviate rejections based on the above references.

Claims 8-10 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Glucksman et al.

Claims 8-10 and 26 are drawn to a polypeptide having at least 60% sequence identity to SEQ ID NO:3 of the instant invention, said polypeptide further comprising heterologous sequences and a pharmaceutical composition comprising said polypeptide and a polypeptide comprising an amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-1639

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." The examiner has broadly interpreted "biological active polypeptide" and "polypeptide having biological activity" to encompass polypeptides having any activity. (See the rejection of the terms "biological active polypeptide" and "polypeptide having biological activity" under 35 USC 112, 2nd paragraph, for Examiner's interpretation of the term.) Therefore, the polypeptides of the claims encompass polypeptides having any function or enzymatic activity, such as sulfatase activity.

Glucksmann et al. (US Patent 7,029,895 B2 – form PTO-892) discloses a polynucleotide encoding a polypeptide having sulfatase activity, wherein said polypeptide is 100% identical to the polypeptide of SEQ ID NO:3 of the instant invention

(Column 119, line 5 through Column 120, line 41 and see attached sequence alignments "Glucksmann et al."). Glucksmann et al. also discloses said polypeptide further comprising heterologous sequences (Column 129, line 64 through Column 131, line 7) and a pharmaceutical composition comprising said polypeptide (Column 165, line 33 through Column 169, line 15). Therefore, the reference of Glucksmann et al. anticipates claims 8-10 and 26.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Examiner notes that Glucksmann et al. does not claim a polypeptide having the amino acid sequence of SEQ ID NO:3, and therefore, there is no double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuno et al. in view of Emerson et al.

Claims 10 and 26 are drawn to a pharmaceutical composition comprising a polypeptide having at least 60% sequence identity to SEQ ID NO:3 and said polypeptide further comprising heterologous peptides.

Kikuno et al. (DNA Res. 1999 Jun 30;6(3):197-205 – form PTO-1449) discloses a polypeptide having 100% sequence identity to SEQ ID NO:3 of the instant invention and has sulfatase activity, as discussed above.

The difference between the reference of Kinuno et al. and the instant invention is that the reference of Kikuno et al. does not teach pharmaceutical composition comprising said polypeptide and said polypeptide further comprising heterologous peptides.

However, Emerson et al. (US Patent 6,562,956 B1 – form PTO-892) discloses a polypeptide having sulfatase activity, wherein said polypeptide further comprises heterologous sequences attached at its N-terminus, a signal peptide to direct said polypeptide to the cell surface (Column 8, lines 15-18) and a pharmaceutical composition comprising said polypeptide, in order to increase levels of said polypeptide to modify growth properties and differentiation of cells (Column 10, lines 26-53).

Therefore, in combining the teachings of Kikuno et al. and Emerson et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to fuse heterologous amino acids at the N-terminus of the polypeptide of Kikuno et al. and to make a pharmaceutical composition comprising the polypeptide of Kikuno et al. using the teachings of Emerson et al. One of ordinary skill in the art would have been motivated to make said constructs in order to direct the polypeptide of Kikuno et al. to the cell surface or to increase the level of the polypeptide of Kikuno et al. to modify growth properties and differentiation of cells One of ordinary skill in the art would have had a reasonable expectation of success of making such constructs since Emerson et al. teaches how to add heterologous amino acids to the N-terminus of a polypeptide and how to make a pharmaceutical composition comprising a sulfatase.

Therefore, the above references render claims 10 and 26 *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-10 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U. S. Patent No. 6,767,727 Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: Claims 8-10 and 26 of the instant application and claims 1-12 of U.S. Patent No. 6,767,727 are both directed to a polypeptide comprising the amino acid sequence of SEQ ID NO:3 and said polypeptide further comprising heterologous amino acid sequences. The polypeptide of SEQ ID NO: 3 of the instant application are 100% identical to the polynucleotide of SEQ ID NO:3 of U.S. Patent No. 6,767,727 (see attached sequence alignments "U.S. Patent No. 6,767,727").

Further, claims 8-10 and 26 of the instant application are drawn to a polypeptide having 60-100% sequence identity to SEQ ID NO: 3, a polypeptide comprising 15 contiguous amino acids of SEQ ID NO:3, allelic variants of SEQ ID NO:3, any of said polypeptide further comprising heterologous amino acid sequences and a pharmaceutical composition comprising any of said polypeptide. Claims 1-12 of U. S.

Patent No. 6,767,727 are drawn to polypeptide having 95-100% sequence identity to SEQ ID NO:3 and a fusion protein comprising said polypeptide. However, a polypeptide having at least 60% sequence identity to SEQ ID NO:3, polypeptide comprising a fragment of SEQ ID NO:3, polypeptide that are allelic variants of SEQ ID NO:3 and a pharmaceutical composition comprising any of said polypeptide are specific embodiments of the polypeptides described in the reference patent. The specification of the reference patent supports a polypeptide having at least 60% sequence identity to SEQ ID NO:3, polypeptide comprising a fragment of SEQ ID NO:3, polypeptide that are allelic variants of SEQ ID NO:3 and a pharmaceutical composition comprising any of said polypeptide (Column 15, line 23 through Column 21, line 32 and Column 29, lines 29-64) that would anticipate the polypeptide of claims 8-10 and the pharmaceutical composition of claim 26. Claims 8-10 and 26 of the instant application cannot be considered patentably distinct over claims 1-12 of the reference application when there is specifically recited embodiment that would anticipate claims 8-10 and 26 of the instant application. Alternatively, claims 8-10 and 26 of the instant application cannot be considered patentably distinct over claims 1-12 of the reference patent because it would have been obvious to one having ordinary skill in the art to modify claims 1-12 of the reference patent by selecting a specifically disclosed embodiment that supports those claimed, i.e. polynucleotide having at least 60% sequence identity to SEQ ID NO:3 One of ordinary skill in the art would have been motivated to do this because the embodiments claimed in the instant claims are disclosed as being a preferred

embodiment within claims 1-12 of the reference patent. Therefore, the conflicting claims are not patentably distinct from each other.

Other Relevant Art

Morimoto et al. (J Biol Chem. 2002 Dec 20;277(51):49175-85. Epub 2002 Oct 3– form PTO-892) discloses a polypeptide having glucoseamine-6-sulfatase activity which is 100% identical to the polypeptide SEQ ID NO:3 of the instant invention (see attached sequence alignment "Morimoto et al.") but is not available as prior art because the reference was published or made known to the public after the instant invention was filed.

Examiner Comment

Examiner notes that there is no double patenting rejection between the instant application and US Patent No. 6,534,302 (issued from application 09/773,426) and US Patent No. 6,780,627 (issued from application 09/495,823) because neither of the issued patents claim polypeptide comprising the amino acid sequence of SEQ ID NO:3 or its variants, but claims subject matter which was restricted from the instant claims and the restriction requirements in both applications were not withdrawn.

Conclusion

Claims 8-10 and 26 are rejected.

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Yong D. Pak
Patent Examiner 1652